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MAY 3, 2021 BY RONNIE

Patty Hajdu Lies: Rigorous Testing WASN'T Required To Get "Vaccines" Onto Market

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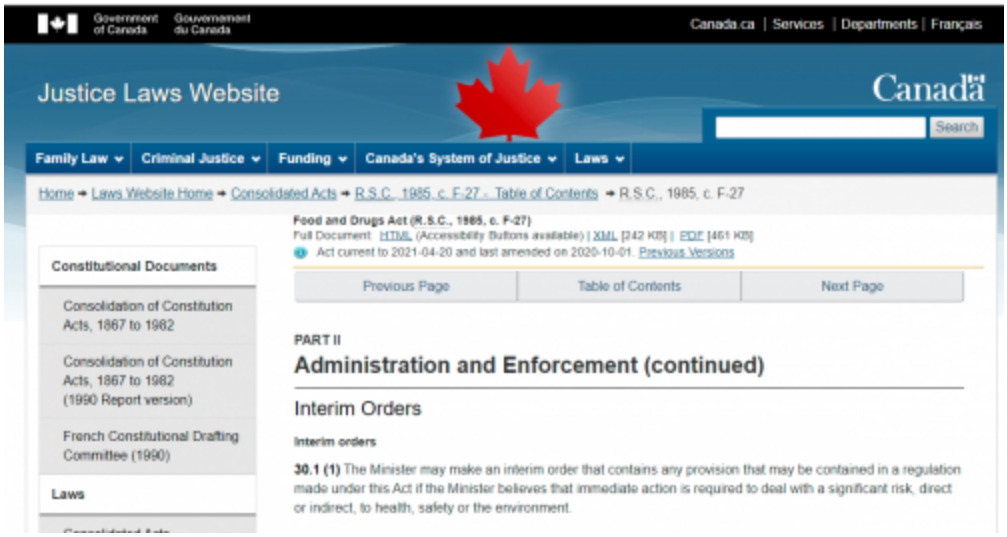
Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
To continue to allow COVID-19 drugs to be imported and sold in Canada, Health Canada has introduced transition measures as of March 18, 2021. The review, authorization and oversight of COVID-19 drugs, including new drugs, will be conducted under the Food and Drug Regulations. For more information, please see the Notice on updated requirements for COVID-19 drug authorizations.
Whereas the Minister of Health believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment;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Constitutional Documents
Consolidation of Constitution Acts, 1867 to 1982
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Interim orders
30.1 (1) The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

Canadians are constantly told that these gene therapy "vaccines" are safe, and have undergone strict testing in order to be allowed on the market. But what exactly are those standards? And is it normal practice to include a clause making authorization mandatory?

People should know that if the product injures or kills them, indemnification agreements prevent the manufacturers from getting sued. A vaccine injury compensation program was announced back in December, but appears to have gone nowhere.

As a reminder, Interim Authorization and Approval are quite different, and cannot be used interchangeably.

(a) Approved: Health Canada has fully reviewed all the testing, and steps have been done, with the final determination that it can be used for the general population
(b) Interim Authorization: deemed to be "worth the risk" under the circumstances, doesn't have to be fully tested. Allowed under Section 30.1 of the Canada Food & Drug Act. Commonly referred to as an emergency use authorization.

If you read the inserts provided by Health Canada (see below), they will all claim to be "authorized under Section 5 of an Interim Order". Fine, but what is that Order, and what does it actually say?

Issuance
5 The ***Minister must issue an authorization*** in respect of a COVID-19 drug if the following requirements are met:

(a) the applicant has submitted an application to the Minister that ***meets the requirements set out in subsection 3(1) or 4(2)***;
(b) the applicant has provided the Minister with all

information or material, ***including samples, requested under subsection 13(1) in the time, form and manner specified under subsection 13(2)***; and
(c) the Minister has ***sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks***, having regard to the ***uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health*** need related to COVID-19.

Several of these "vaccines", and I use the term loosely, were given Interim Authorization under Section 5 of an Interim Order signed by Health Minister Patty Hajdu on September 16, 2020. The above criteria is all that is required.

Note: Section 5 starts out with "The Minister must" issue and authorization. It's not that "The Minister should", or "The Minister may" issue one, but the Minister MUST.

Also, the above requirements are not very strict. 3(1) or 4(2) must be met, along with 13(1) and 13(2). And all that's needed is the very subjective standard that the "Minister has sufficient evidence to support the conclusion". It doesn't specify what, if any, standard there is. The Minister only needs to see is as "worth the risk" given the uncertainties there are.

It's worth noting that Health Canada doesn't do the testing themselves. Instead, they rely heavily on the documentation provided. Quite the trust system.

> Application for authorization
> 3 (1) Subject to section 4, an application for an authorization in respect of a COVID-19 drug must be in a form established by the Minister and contain sufficient information and material

to enable the Minister to determine whether to issue the authorization, including

.

(a) the ***applicant's name and contact information and, in the case of a foreign applicant, the name and contact information of their representative in Canada***;

(b) a description of the drug and a statement of its proper name or its common name if there is no proper name;

(c) a statement of the brand name of the drug or the identifying name or code proposed for the drug;

a ***list of the ingredients of the drug, stated quantitatively***;

(d) the ***specifications for each of the drug's ingredients***;

(e) a description of the facilities and equipment to be used in the manufacture, preparation and packaging of the drug;

(f) ***details of the method of manufacture and the controls to be used*** in the manufacture, preparation and packaging of the drug;

(g) ***details of the tests to be applied to control the potency, purity, stability and safety of the drug;***

(h) the names and qualifications of all the investigators to whom the drug has been sold;

(i) a draft of every label to be used in connection with the drug, including any package insert and any document that (j) is provided on request and that sets out supplementary information on the use of the drug;

(k) a statement of all the representations to be made for the promotion of the drug respecting

(i) the recommended route of administration of the drug,

(ii) the proposed dosage of the drug,

(iii) the drug's indications, and

(iv) the ***contra-indications and side effects of the drug***;

(l) a description of the dosage form that is proposed for the sale of the drug;

(m) evidence that all test batches of the drug used in any studies conducted in connection with the application ***were manufactured and controlled in a manner that is representative of market production***;

(n) in the case of a drug intended for ***administration to food-producing animals***, the withdrawal period of the drug; and

(o) the ***known information in relation to the quality, safety and effectiveness of the drug***.

About part (n), it says "administration to food-producing animals". Are we to assume that livestock are going to be vaccinated with these substances at some point? Or are we repurposing drugs that were originally meant for them? That's a bit unsettling.

> Application for authorization – ***foreign drug***
> 4 (1) An application for an authorization in respect of a COVID-19 drug may be based on a comparison to a foreign drug if the sale of the foreign drug is authorized by a foreign regulatory authority on the basis of information submitted to the authority in relation to the quality, safety and effectiveness of that drug.
> .
> Content
> (2) The application must be in a form established by the Minister and contain the following information and material:
> .
> (a) the information and material described in ***paragraphs 3(1)(a) to (d), (f), (j) to (l) and, if applicable, (n);***
> (b) an attestation, signed and dated by an individual who has authority to bind the applicant in Canada, certifying that the applicant has access to the information referred to in paragraph 3(1)(o) that was submitted to the relevant foreign regulatory authority in order for the foreign drug to be authorized to be sold;
> (c) information that ***demonstrates that the drug is identical to, and is manufactured, prepared and packaged in the same manner as, the foreign drug***;
> (d) information that demonstrates that the sale of the foreign drug is ***authorized by the foreign regulatory authority referred to in paragraph (b)***; and
> (e) any labels that are approved by the foreign regulatory authority referred to in paragraph (b) for use in connection with the foreign drug.

> Request for information or material
> 13 (1) The Minister may request that a person that has submitted an application for an authorization in respect of a COVID-19 drug or the holder of such an authorization ***provide any information or material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or suspend the authorization.***
> .
> Time, form and manner
> (2) The person or holder, as the case may be, ***must provide the information, material or samples in the time, form and manner specified by the Minister***.

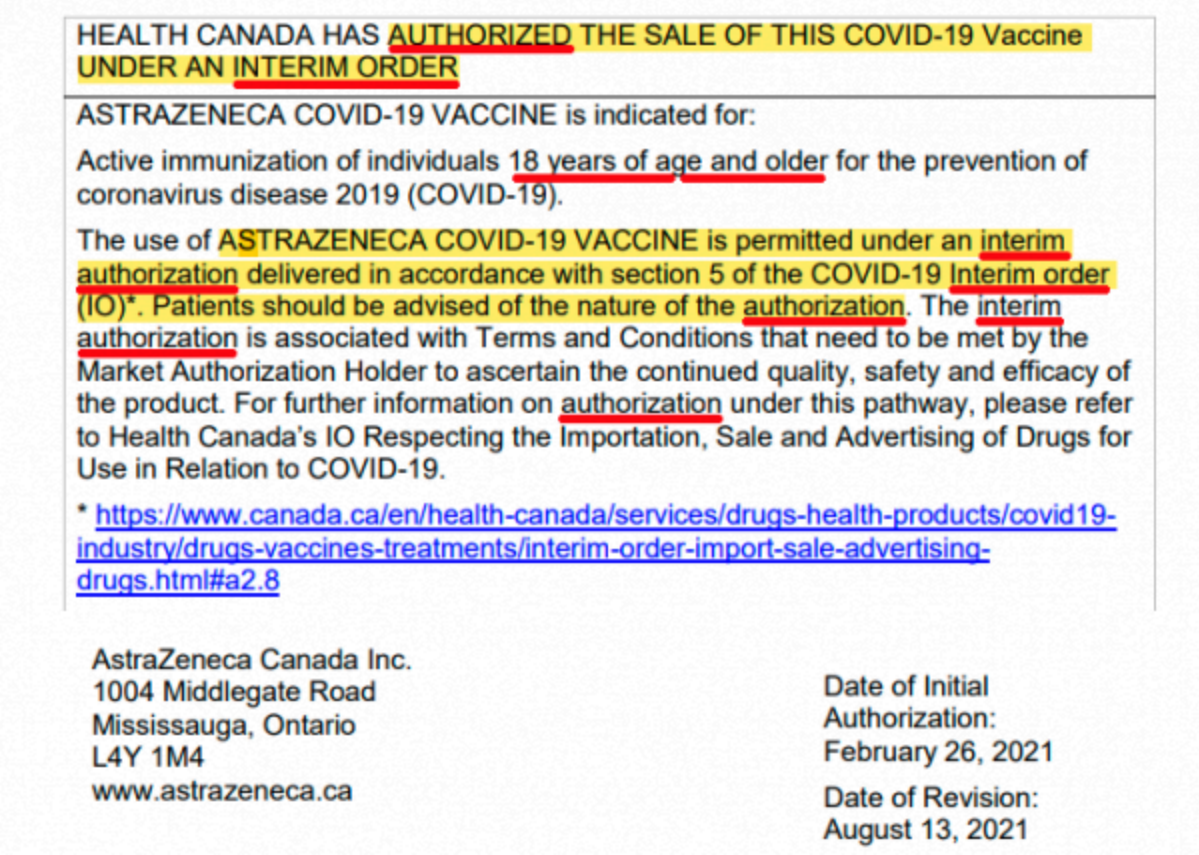
Section 3(1) lists what documentation needs to be submitted to get authorization. Section 4(2) contains a few extra steps for foreign drugs. Sections 13(1) and (2) state that information and samples must be provided if demanded.

The standard for Interim Authorization under Section 5 appears to be a fairly low one. Keep in mind, the Minister doesn't even need to be certain the drugs work as advertised. It just has to be determined to be worth the risk. Not quite what we are told on the news.

As for the basis in the law, Section 30.1 of the Canada Food & Drug Act allows the Health Minister to sign such Orders, if it's believed, (or claimed to be believed), it's in the public interest. There is no requirement that the Minister have any appropriate education background, or know what he/she is talking about.

Circling back to the top of Section 5, the Health Minister "must issue an authorization" if the conditions in Section 5 are met?!?! So this isn't discretionary? Our graphic designer Minister must sign off on this?

It's also unsettling that this Order allows for drugs originally intended for livestock to be repurposed and tested on humans.



HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 Vaccine UNDER AN INTERIM ORDER

ASTRAZENECA COVID-19 VACCINE is indicated for:

Active immunization of individuals 18 years of age and older for the prevention of coronavirus disease 2019 (COVID-19).

The use of ASTRAZENECA COVID-19 VACCINE is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

* https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, Ontario
L4Y 1M4
www.astrazeneca.ca

Date of Initial Authorization:
February 26, 2021

Date of Revision:
August 13, 2021

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 Vaccine UNDER AN INTERIM ORDER

Janssen COVID-19 Vaccine is indicated for:

Active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

The use of Janssen COVID-19 Vaccine is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

* https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html

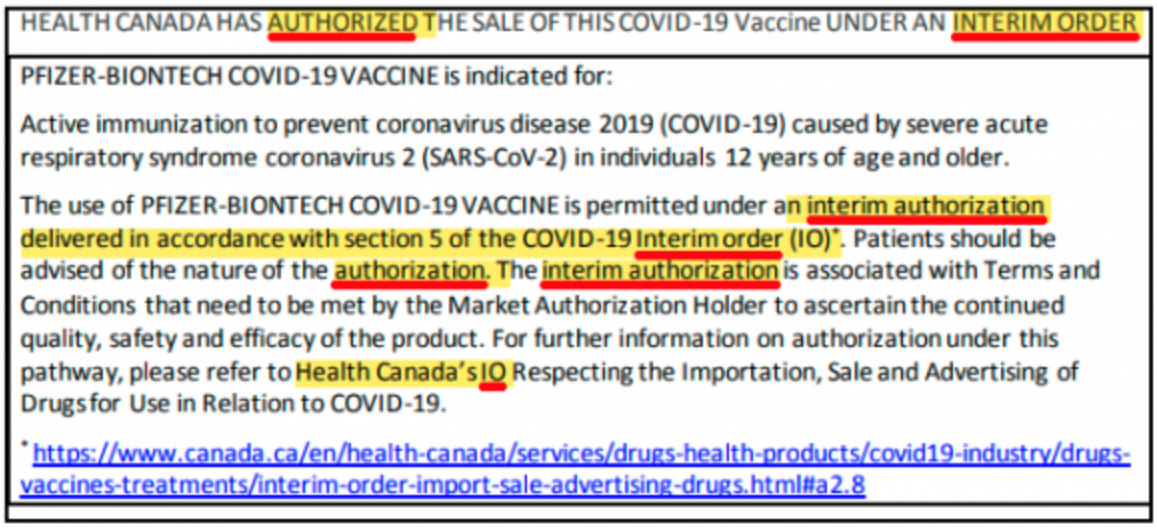
HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 Vaccine UNDER AN INTERIM ORDER

COVID-19 Vaccine Moderna is indicated for:

Active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 12 years of age and older.

The use of COVID-19 Vaccine Moderna is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

* https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8



HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 Vaccine UNDER AN INTERIM ORDER

PFIZER-BIONTECH COVID-19 VACCINE is indicated for:

Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

The use of PFIZER-BIONTECH COVID-19 VACCINE is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

* https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8

WHO Paper On MANDATORY Vaccination April 13, 2021 (Original)
WHO Paper On MANDATORY Vaccination April 13, 2021 (Copy)
Section 30.1 Canada Food & Drug Act
September 2020 Interim Order From Patty Hajdu
https://www.canada.ca/en/public-health/news/2020/12/government-of-canada-announces-pan-canadian-vaccine-injury-support-program.html
https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf
https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf
https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf
https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

Testing Product Insert AstraZeneca Interim Authorization
Testing Product Insert Janssen Interim Authorization
Testing Product Insert Moderna Interim Authorization
Testing Product Insert Pfizer Interim Authorization

Vaccines Supported For Pregnant Women, Despite No Testing
Vaccines Given "Interim Authorization", Not Approval. Very Different
Call Centers Wrongly Telling People "Vaccines" Are Approved
Ontario Adds, Then Removes Protections Against "No Jab, No Job"
WHO April 13 Paper: Discussion On Mandatory "Experimental Vaxx"

CANADA, DRUGS/ALCOHOL, GLOBALISM, HEALTH, HUMAN RIGHTS, NGO/CS, UN/WHO, VACCINES

2 Replies to "Patty Hajdu Lies: Rigorous Testing WASN'T Required To Get "Vaccines" Onto Market"

ginunn

MAY 3, 2021 AT 11:32 AM

Hi. I'm more familiar with the CDC process. As I understand it, Moderna and Pfizer submitted results from early phase 1-3 trials and were granted emergency use authorization based on these tests. These tests (phase 3 ongoing) had very specific and well defined dosage and distance between 2nd dose application, i.e. 28 days. In clinical studies like these, 28 days is exactly 28 days and not 27 or 29, otherwise study results are invalid.

So presumably, if an authority came along and said our scientists think 4 months between doses is fine, such would be outside the conditions that authorization was granted under, making such use illegal.

As I said, I have not dug into this issue but you may have considered this.
On a separate note, i have a friend in Chicago, Vanne, who says he knows you and that you have published some of his work. If there's anything on my website that you wish to use or republish, please feel free. My latest blog article is The Canadian Climate Model, CanESM5: Running Hot (https://thepoog.com/wp/2021/04/30/the-canadian-climate-model-canesm5-running-hot/).

The Project Veritas CNN expose revealed the redirection the global elite are taking back towards the climate "emergency", presumably with a new paint job.

Ian Nunn (The POOG).

Ed Thompson

MAY 3, 2021 AT 12:47 PM

Useful information about the quality of the PfizerBioNTech vaccines from Reiner Fuellmich's Corona Ausschuss.
http://enformtk.u-aizu.ac.jp/howard/gcep_dr_vanessa_schmidt_krueger/?s=09